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Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SCHERING-PLOUGH HEALTHCARE PRODUCTS, INC., SANTARUS, INC., and THE CURATORS OF THE UNIVERSITY OF MISSOURI,	)	
Plaintiffs,	)	Civil Action No.: _____
v.	)	***Document electronically filed.***
PAR PHARMACEUTICAL, INC.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Schering-Plough HealthCare Products, Inc. ("Schering-Plough"), Santarus, Inc. ("Santarus"), and The Curators of the University of Missouri (the "University") (collectively

"Plaintiffs") hereby assert the following claims for patent infringement against Defendant Par Pharmaceutical, Inc. ("Par"), and allege as follows:

THE PARTIES

1. Schering-Plough is a corporation organized and existing under the laws of Delaware with its principal place of business at 3030 Jackson Avenue, Memphis, TN 38151. Schering-Plough is a subsidiary of Merck & Co., Inc., which has its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

2. Santarus is a corporation organized and existing under the laws of Delaware, having a principal place of business at 3721 Valley Centre Drive, Suite 400, San Diego, California 92130.

3. The University is a public corporation and body politic, an arm or instrumentality of state government in the state of Missouri, having a place of business at 321 University Hall, Columbia, Missouri 65211.

4. On information and belief, Par is a corporation organized and existing under the laws of Delaware with a principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677. On information and belief, Par is engaged in the manufacturing, marketing and sale of generic pharmaceutical products in the United States, including in the District of New Jersey, and conducts business throughout the United States.

NATURE OF THE ACTION

5. This is a civil action for the infringement of United States Patent Nos. 6,699,885, 6,489,346, 6,645,988, and 7,399,772 (collectively "the Patents-in-Suit"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 et seq.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over the matters asserted herein under 28 U.S.C. §§ 1331 and 1338(a).

7. Par is subject to personal jurisdiction in this District because it has its principal place of business in Woodcliff Lake, New Jersey, conducts business in this District, purposefully avails itself of the rights and benefits of New Jersey law, and has substantial and continuing contacts with New Jersey.

8. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

THE PATENTS

9. On March 2, 2004, the United States Patent and Trademark Office (the "PTO") issued U.S. Patent No. 6,699,885 (the "'885 Patent"), entitled "Substituted Benzimidazole Dosage Forms and Methods of Using Same" to the University, the assignee of the named inventor Jeffrey O. Phillips. Since March 2, 2004, the University has been, and continues to be, the sole owner of the '885 Patent. A copy of the '885 Patent is attached hereto as Exhibit A.

10. On or about August 22, 2005, a third party requested reexamination of the '885 Patent by the PTO, which was granted by the PTO. On or about March 13, 2007, the reexamination proceedings concluded with the PTO issuing a Notice of Intent to Issue a Reexamination Certificate confirming that all claims of the '885 Patent "are determined to be patentable as amended." On September 18, 2007, the PTO issued a Reexamination Certificate confirming that all claims as amended are "determined to be patentable." In the Reexamination Certificate, claims 1 and 26 were amended, and claims 52 and 53 were added. A copy of the Ex Parte Reexamination Certificate (5894th) for the '885 Patent is attached hereto as Exhibit B.

11. On December 3, 2002, the PTO issued U.S. Patent No. 6,489,346 (the "'346 Patent"), entitled "Substituted Benzimidazole Dosage Forms and Method of Using Same" to the University, the assignee of the named inventor Jeffrey O. Phillips. Since December 3, 2002, the University has been, and continues to be, the sole owner of the '346 Patent. A copy of the '346 Patent is attached hereto as Exhibit C.

12. On November 11, 2003, the PTO issued U.S. Patent No. 6,645,988 (the "'988 Patent"), entitled "Substituted Benzimidazole Dosage Forms and Method of Using Same" to the University, the assignee of the named inventor Jeffrey O. Phillips. Since November 11, 2003, the University has been, and continues to be, the sole owner of the '988 Patent. A copy of the '988 Patent is attached hereto as Exhibit D.

13. On July 15, 2008, the PTO issued U.S. Patent No. 7,399,772 (the "'772 Patent"), entitled "Substituted Benzimidazole Dosage Forms and Method of Using Same" to the University, the assignee of the named inventor Jeffrey O. Phillips. Since July 15, 2008, the University has been, and continues to be, the sole owner of the '772 Patent. A copy of the '772 Patent is attached hereto as Exhibit E.

14. Santarus is the exclusive licensee under the Patents-in-Suit for Santarus' ZEGERID brand prescription pharmaceutical products. Schering-Plough obtained an exclusive license under the Patents-in-Suit from Santarus for Schering-Plough's ZEGERID OTC (omeprazole 20 mg/sodium bicarbonate 1100 mg) Capsules product ("ZEGERID OTC"). Plaintiffs have the right to sue to enforce the Patents-in-Suit.

15. The Patents-in-Suit are listed in the United States Food and Drug Administration's (the "FDA") *Approved Drug Products with Therapeutic Equivalence Evaluations,*

commonly known as the Orange Book, in support of ZEGERID OTC. ZEGERID OTC is marketed by Schering-Plough.

ACTS GIVING RISE TO THIS ACTION

16. On information and belief, on or before August 6, 2010, Par submitted Abbreviated New Drug Application No. 201946 (the "Par ANDA") to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The Par ANDA seeks approval to engage in the commercial manufacture, use, offer for sale, and/or sale of a generic omeprazole and sodium bicarbonate capsules, 20 mg/1100 mg (the "Proposed Par Capsules"), a generic version of ZEGERID OTC. The Par ANDA specifically seeks FDA approval to market the Proposed Par Capsules prior to the expiration of the Patents-in Suit.

17. Plaintiffs received a letter dated August 6, 2010, from Par notifying them that the Par ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Par Paragraph IV Certification") that, in Par's opinion, the Patents-in-Suit are invalid, unenforceable or will not be infringed by the commercial manufacture, use or sale of the Proposed Par Capsules.

18. Plaintiffs commenced this action within 45 days of receiving the Par Paragraph IV Certification.

FIRST CLAIM FOR RELIEF

INFRINGEMENT OF THE '885 PATENT

19. Plaintiffs incorporate by reference paragraphs 1 through 18.

20. The submission of the Par ANDA to the FDA, including the Par Paragraph IV Certification, constitutes infringement of the '885 Patent under 35 U.S.C. § 271(e)(2)(A). Moreover, any commercial manufacture, use, offer to sell, sale or import of the Proposed Par Capsules, or any inducement of or contribution to such conduct during the term of the '885 Patent would further infringe the '885 Patent under 35 U.S.C. § 271(a)–(c).

21. Par had actual and constructive notice of the '885 Patent prior to filing the Par ANDA.

22. Par's infringing activities will irreparably harm Plaintiffs unless enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

SECOND CLAIM FOR RELIEF

INFRINGEMENT OF THE '346 PATENT

23. Plaintiffs incorporate by reference paragraphs 1 through 18.

24. The submission of the Par ANDA to the FDA, including the Par Paragraph IV Certification, constitutes infringement of the '346 Patent under 35 U.S.C. § 271(e)(2)(A). Moreover, any commercial manufacture, use, offer to sell, sale or import of the Proposed Par Capsules, or any inducement of or contribution to such conduct during the term of the '346 Patent would further infringe the '346 Patent under 35 U.S.C. § 271(a)–(c).

25. Par had actual and constructive notice of the '346 Patent prior to filing the Par ANDA.

26. Par's infringing activities will irreparably harm Plaintiffs unless enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

THIRD CLAIM FOR RELIEF

INFRINGEMENT OF THE '988 PATENT

27. Plaintiffs incorporate by reference paragraphs 1 through 18.

28. The submission of the Par ANDA to the FDA, including the Par Paragraph IV Certification, constitutes infringement of the '988 Patent under 35 U.S.C. § 271(e)(2)(A). Moreover, any commercial manufacture, use, offer to sell, sale or import of the Proposed Par Capsules, or any inducement of or contribution to such conduct during the term of the '988 Patent would further infringe the '988 Patent under 35 U.S.C. § 271(a)–(c).

29. Par had actual and constructive notice of the '885 Patent prior to filing the Par ANDA.

30. Par's infringing activities will irreparably harm Plaintiffs unless enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

FOURTH CLAIM FOR RELIEF

INFRINGEMENT OF THE '772 PATENT

31. Plaintiffs incorporate by reference paragraphs 1 through 18.

32. The submission of the Par ANDA to the FDA, including the Par Paragraph IV Certification, constitutes infringement of the '772 Patent under 35 U.S.C. § 271(e)(2)(A). Moreover, any commercial manufacture, use, offer to sell, sale or import of the Proposed Par Capsules, or any inducement of or contribution to such conduct during the term of the '772 Patent would further infringe the '772 Patent under 35 U.S.C. § 271(a)–(c).

33. Par had actual and constructive notice of the '885 Patent prior to filing the Par ANDA.

34. Par's infringing activities will irreparably harm Plaintiffs unless enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that:

1. Judgment be entered that Par has infringed the Patents-in-Suit;

2. Judgment be entered that the commercial use, sale, offer for sale, manufacture, and/or importation by Par of the Proposed Par Capsules would infringe the Patents-in-Suit;

3. An order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of the Par ANDA, under § 505(j) of the Federal Food, Drug and Cosmetic Act

(21 U.S.C. § 355(j)), be a date which is not earlier than the expiration date of the Patents-in-Suit, including any extensions;

4. That Par, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, are preliminarily and permanently enjoined from commercially manufacturing, using, offering to sell, or selling the Proposed Par Capsules within the United States, or importing the Proposed Par Capsules into the United States, prior to the expiration of the Patents-in-Suit, including any extensions; and

5. Such other and further relief as the Court may deem just and proper under the circumstances.

Respectfully submitted,

GIBBONS P.C.

Dated: September 20, 2010
Newark, New Jersey

s/ Sheila F. McShane

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